

REMARKS/ARGUMENTS

Applicants wish to thank Examiner Holly Schnizer for kindly suggesting replacement claim language, as discussed below.

Entry of the instant amendment, after final rejection, is requested as it places the subject application in form for allowance, as explained below.

Claims 78-94, presented hereby, are pending in this application.

Cancel claims 60-77 are cancelled, hereby, without prejudice or disclaimer.

Claims 78-94 correspond to claims 60-64 and 66-77, respectively, amended as explained below.

Claim 62 is amended, as claim 80, by changing "-butyl-n" to read "n-butyl-."

Claim 82 revises claim 64 by limiting the "treatment" to "insulin-independent diabetes mellitus."

Claim 83 revises claim 66 by changing "in a release form by which the releases is attained" to read "wherein the composition is administered".

Claim 84 revises claim 67, by changing "suitable for subcutaneous, intravenous, peroral, intramuscular or transpulmonary administration" to read "wherein the composition is administered subcutaneously, intravenously, perorally, intramuscularly or transpulmonarily".

Claim 78 corresponds to claim 60. Claims 79, 81, and 85-94 correspond to former claims 61, 63, and 68-77, revised to be dependent, directly or indirectly, on claim 78.

There are four rejections of record outstanding: (1) alleged lack of enablement under section 112, first paragraph; (2) alleged lack of novelty (anticipation) under section 102(b) based on EP 619322 (Danley); (3) alleged anticipation under section 102(b) based on U.S. 518,666 (Habener); and (4) alleged indefinite language under section 112, second paragraph.

Method claims 64-67 and *composition* claims 68-77 stand rejected under 35 USC 112, first paragraph, for allegedly lacking enablement. Reconsideration is requested.

As applied against the *composition* claims, the rejection is poorly taken. First of all, the statement of rejection (implicitly) acknowledges enablement of compound claims 60-63. Since each of composition claims 68-77 is based on either compound claim 60 or compound claim 61, enablement must *per se* exist for the composition claims.

Secondly, the rejection of the composition claims for alleged lack of enablement is improper, because the statement of rejection fails to apply the correct standard for determining enablement under section 112. The rejection of composition claims is based on alleged lack of enablement for non-claimed *uses* of the composition, i.e., treating specific disease *disclosed* in the specification, but not *claimed*. When "the claims . . . do not require the use . . . in dispute," enablement of the *use* "is not an issue [under section 112, first paragraph]." *Ex parte Erlich*, USPQ2d 1011, 1014 (BPA&I 1987). In the case of the present composition claims, since the uses allegedly lacking enablement are not "required" by the rejected composition claims, the statement of rejection has failed to support the rejection of these claims.

With respect to the method of treatment claims 64-67, the instant amendment limits the claims to the method of treatment acknowledged as "being enabling," i.e., the therapy of insulin-independent diabetes mellitus.

Accordingly, the rejection under 35 USC 112, first paragraph, is in order for withdrawal.

Claims 60-62, 64, and 66-77 stand rejected under 35 USC 102(b) based on Danley. Reconsideration is requested.

The rejection is poorly taken. The statement of rejection relies on a compound in the cited reference (SEQ ID NO: 5) that has only the "identical *general formula*" of the presently claimed compound. However, the presently claimed compound is *not identical* to the recited "general formula"; a feature (limitation) on the presently claimed compound is *the amide modification at the C-terminus*. Since the limitation to an *amide modification at the C-terminus* does no "identically appear" in the reference disclosure, the reference does not anticipate the claims *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). The absence from the Danley of the "single" claim limitation negates anticipation of the claims by the reference. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). Since the Danley compound relied on does not represent *all* limitations of the claimed compound, as arranged in the claimed compound, the reference compound does not anticipate the presently claimed compound. *Jamesbury Corp. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). A reference that discloses "substantially the same invention" does not anticipate the claimed invention. *Id.*

Claims 60-62, 64, and 66-77 stand rejected under 35 USC as allegedly anticipated by US 5,118,666 (Habener). Reconsideration is requested.

The aforesaid analysis in connection with the rejection based on Danley is, essentially, applicable to the rejection based on Habener. Again, the statement of rejection relies on a reference compound that is not identical to the presently claimed compound, but only identical to a part of the claimed compound, i.e., the reference compound is allegedly identical only with respect to the "general formula" of the presently claimed compound.

That is, a limitation on the presently claimed compound – *the amide modification at the C-terminus* – does not "identically appear" in the Habener disclosure and, so, the reference does not anticipate the claims *Gechter*, 43 USPQ2d at 1032 (*emphasis added*). The absence from Habener of the "single" claim limitation negates anticipation of the claims by the reference. *Kolster Speedsteel A B, supra*. Since the Habener compound relied on does not represent *all* limitations of the presently claimed compound, as arranged in the claimed compound, the reference compound does not anticipate the presently claimed compound. *Jamesbury Corp., supra*. A reference that discloses "substantially the same invention" does not anticipate the claimed invention. *Id.* Accordingly, the rejection based on Habener is in order for withdrawal.

Claims 62, 66, and 67 were rejected under 35 USC 112, 2nd paragraph, for allegedly being indefinite. Reconsideration is requested.

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The rejection is based on a clerical error as it is applied against claim 62. Changing "-butyl-n" in claim 62 to read "n-butyl," in present corresponding claim 80, as helpfully suggested by the Examiner, overcomes the rejection against claim 62.

As applied against claims 66 and 67, the claim language is revised, hereby, in present corresponding claims 83 and 84, as helpfully suggested by the Examiner. Accordingly, the rejection as applied against claims 66 and 67 is overcome.

Favorable action is requested.

Respectfully submitted,

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